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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,404	06/11/2007	Jason Lye	KCX-959-PCT-US (19611.1)	3763
23556 7590 10/02/2008 KIMBERLY-CLARK WORLDWIDE, INC. Catherine E. Wolf 401 NORTH LAKE STREET NEENAH, WI 54956			EXAMINER HOBBBS, LISA JOE	
			ART UNIT 1657	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/581,404	Applicant(s) LYE ET AL.	
	Examiner Lisa J. Hobbs	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

Claim Status

Claims 1-20 are active in the case. Claims 1-20 are under examination; no claims are withdrawn as drawn to a non-elected invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 17, 18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 6-17 of copending Application No.

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11/513,500. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications recite methods of detecting fungi comprising contacting a surface with a detector and observing color changes when microbes are present.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 17-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-31 of copending Application No.

11/303,001. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications recite methods of detecting fungi comprising contacting a surface with a detector and observing color changes when microbes are present.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 17, 19-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No.

11/847,569. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications recite methods of detecting fungi comprising contacting a surface with a detector and observing color changes when microbes are present.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Claims 14-15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 6, 11-20 of U.S. Patent No. 7,282,349.

Although the conflicting claims are not identical, they are not patentably distinct from each other because all claims recite products, including wipes and tissue, which comprise a dye that reacts in the presence of bacteria and provides a visual change for recognition of bacterial contamination.

Claims 14-15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No. 7,300,770. Although the conflicting claims are not identical, they are not patentably distinct from each other because all claims recite products, including wipes and tissue, which comprise a dye that reacts in the presence of bacteria and provides a visual change for recognition of bacterial contamination.

Claims 17-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1, 14 of U.S. Patent No. 7,399,608. Although the conflicting claims are not identical, they are not patentably distinct from each other because all claims recite products, including wipes and tissue, which comprise a dye that reacts in the presence of bacteria and provides a visual change for recognition of bacterial contamination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 12-15, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Berger et al. (US 3,496,066). Berger et al. teach a “diagnostic agent for use in the detection of bacteria” wherein “the presence or absence of color formation, as well as the degree thereof, being directly related to the amount, if any, of the bacteria present” (col. 1-2 bridging paragraph). They teach that the detection “is carried out by bringing together the biological fluid to be investigated with a liquid or a solid [agar gel, see col. 4, lines 58-60] nutrient medium and a non-growth inhibiting amount of a [dye] compound” (col. 3, lines 65-68). They also discuss that “an upper limitation of the amount of [dye] compounds...to be added is necessary because the compounds possess certain bactericidal or bacteriostatic properties (col. 4, lines 38-40, also see lines 17-23). As well, they teach “tablets” of “filter paper strips” which comprise the dye compounds (col. 4, lines 63-65).

Claim 1-3, 6-9, 11-13, 16-17, 19-20 rejected under 35 U.S.C. 102(b) as being anticipated by Inoue (JP 11083849). Inoue teaches a composition wherein urine is dyed with a dyeing agent and passed through flow cytometry where it is irradiated with green light. The amount of scattered light and fluorescence emitted from the dyed formed element is measured. [Wherein] the dyeing agent is...merocyanine" dyes (abstract).

Claims 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Irish. Irish teaches a “method of determining the quantity of living organisms at the surface of an object” by

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spraying a bioluminescent agent onto the surface and then monitoring the amount of fluorescence to correlate with the quantity of bacteria present (abstract).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berger et al., Inoue, Irish, and LaClair (US 5,958,673 A). As discussed above, Berger et al. teach compositions and methods of detecting bacterial presence visually, including the creation of test strips, using gels and liquids wherein the coloration is proportional to the bacterial presence. Inoue teaches bacterial detection in liquids using a flow-through apparatus and merocyanine dyes. Irish teaches methods and compositions for bacterial detection comprising spraying reagents of interest onto objects and detecting the resultant fluorescence. Berger et al. particularly teach that the detection properties of the compositions and methods can be combined with bacteriocidal and bacteriostatic properties and that one might "carry out quantitative and semi-quantitative individual determinations of special types of microorganisms" without expense and undue effort (col. 5, line 17) and they teach that a range of bacterial concentrations can be used in the instant method of detection and that the amount of colorant necessary for the desired detection can be easily determined (Example 1).

LaClair teaches that "[f]luorescent dyes possess reactive linkers for conjugating to nucleic acids, carbohydrates and peptides. The conjugates fluoresce in the visible and UV spectrum and have an excellent solvchromatic response as compared to other fluorescence or chromatic labels. The conjugates are stable but also have medium sensitive. The fluorescent dyes have little triplet state formation and are not photoreactive, making them an excellent substance for biological investigations. Uses for the dyes include protein labelling, DNA labelling, single molecule spectroscopy and fluorescence. A synthesis of the dyes is disclosed. Methods of use include the detection of carbohydrate-protein interactions" (abstract) and that has been an increased interest in carbohydrate-protein interactions "due to the participation of these events in

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a wide variety of disease related processes including: cellular growth-development, fertilization, metastasis, inflammatory response, as well as bacterial and viral recognition” (col. 2, lines 5-10). He also teaches “[c]harge transfer labels, such as 5-(dimethylamino)-1-naphthalenesulfonyl or dansyl chloride, have been extensively used for the detection, characterization and localization of carbohydrates, phospholipids, proteins, oligonucleotides as well as numerous other synthetic and natural materials. These materials typically experience a shift in their UV/visible absorption and/or fluorescence spectra with respect to the nature of their solvent shell” (col. 3, lines 54-65).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Berger et al., Inoue, Irish, and LaClair to achieve the instant invention as recited. One would have reasonable expectation of success in that Berger et al., Inoue and Irish teach multiple variants on the dyes that can be used and methods that can be employed to expose the microbe of interest to the dye. As well, LaClair teaches a new class of dyes for microbe detection that are based on carbohydrate-protein surface adhesion.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa J. Hobbs whose telephone number is 571-272-3373. The examiner can normally be reached on Monday to Friday, 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lisa J. Hobbs/
Primary Examiner
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ljh